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October 14, 1988

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Alphonse R. Noe, Manager
Patent Law Department
AMERICAN CYANAMID COMPANY
1937 West Main Street
P.O. Box 60
Stamford, CT 06904-0060

RE: Patent Term Extension
Application for
U.S. Patent No. 4,278,689
Issued: July 14, 1981

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,278,689 issued July 14, 1981, is eligible for patent term extension under 35 USC 156. The period of extension has been determined to be two (2) years.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register on March 30, 1988 as follows:

$$\begin{aligned} \text{Period} &= 1/2 \text{ (Testing Phase)} + \text{Approval Phase} \\ &= 1/2 (1034) + 1309 \\ &= 1826 \text{ days} \end{aligned}$$

Since the regulatory review period began (May 16, 1979) before the patent issued (July 14, 1981), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the determination of the length of the extension period. 35 U.S.C. 156(c) (From May 16, 1979 to July 14, 1981 is 790 days; this period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period: 1836-790=1034 days). No determination of a lack of due diligence was made. The exception of 35 USC 156(c)(3) does not operate to reduce the period determined above. The limitation of 35 USC 156(g)(4)(c) applies in the present situation because Patent No. 4,278,689 was issued (July 14, 1981) before the date of enactment (September 24, 1984) of 35 USC 156; the date of exemption under Section 505(i) of the Federal Food, Drug and Cosmetic Act involving Novantrone became effective (May 16, 1979), was before date of enactment, and the product was not approved for commercial marketing or use (December 23, 1987) before the date of enactment. Since the period of extension calculated under 35 USC 156(c) for Patent No. 4,278,689 and Novantrone cannot exceed two (2) years under 35 USC 156(g)(4)(C), the period of extension will be for two (2) years.

A single request for reconsideration of this final determination as to eligibility and the length of extension of the term of U.S. Patent 4,278,689 may be made if filed within one (1) month of the date of this notice. 37 CFR 1.136(a) is not applicable to this time period. It is noted that the applicant for extension of the term of Patent No. 4,278,689 has filed an application for extension of the term of Patent No. 4,197,249, also to the product Novantrone. Only one patent may be extended for any product. 35 USC 156(c) 4. In the absence of an election by applicant, and in accordance with 37 CFR 1.785 (b), if applications are filed for extension of the terms of different patents based upon the same regulatory review period for a product, the certificate of extension of patent term will be issued to the patent having the earliest date of issuance (4,197,249). If issuance of the certificate of extension on U.S. Patent 4,278,689 occurs, the following information will be published in the Official Gazette:

U.S. Patent No. 4,278,689, granted
July 14, 1981 to Keith C. Murdock et al
Owner of Record: American Cyanamid Company
Title: 1,4-BIS(SUBSTITUTED-AMINO)-5,8-DIHY-
DROXY-ANTHRAQUINONES AND LEUCO BASES
THEREOF
Classification: 514-656
Product Trade Name: Novantrone
Term Extended: 2 years

C.E.Van Horn

Charles E. Van Horn
Deputy Solicitor
Patent & Trademark Office

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

RE: Novantrone
FDA Docket # 88E-0067